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1IN THE UNITED STATES DISTRICT COURT FOR

2THE DISTRICT OF SOUTH DAKOTA

3

4TERRI BRUCE,)

5Plaintiff,)

6vs.) No. 17-5080

7STATE OF SOUTH DAKOTA and)

8LAURIE GILL, in her official)

9capacity as Commissioner of)

10of the South Dakota Bureau)

11of Human Resources,)

12Defendants.)

13

14DEPOSITION OF DR. PAUL W. HRUZ, M.D., Ph.D.

15TAKEN ON BEHALF OF THE PLAINTIFF

16JULY 16, 2018

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19(Starting time of the deposition: 8:49 a.m.)

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13

14

15Deposition of DR. PAUL W. HRUZ, M.D.,

16Ph.D., produced, sworn and examined on the 16th

17Day of July, 2018 between the hours of 9:00 a.m.

18and 5:00 p.m. at the offices of Alaris Litigation

19Services, 711 N. 11th Street, in the City of St.

20Louis, State of Missouri, before Rebecca Brewer,

21Registered Professional Reporter, Certified

22Realtime Reporter, Missouri Certified Shorthand

23Reporter, and Notary Public within and for the

24State of Missouri.

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23be copied and attached to the transcript.)

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1APPEARANCES

2FOR THE PLAINTIFF:

3Ms. Leslie Cooper

4Mr. Joshua A. Block

5American Civil Liberties Union Foundation

6125 Broad Street, 18th Floor

7New York, New York, 10004

8Lcooper@aclu.org

9Jblock@aclu.org

10

11FOR THE DEFENDANT:

12Mr. Jerry D. Johnson

13Jerry Johnson Law Office

14909 St. Joseph Street, Suite 800

15Rapid City, South Dakota, 57701

16Jdjbck@aol.com

17

18

19

20

21Ms. Rebecca Brewer, RPR, CCR, CRR

22Alaris Litigation Services

23711 North Eleventh Street

24St. Louis, Missouri, 63101

25(314) 644-2191

<p style="text-align: right;">Page 13</p> <p>1 A Definitely, yes.</p> <p>2 Q Okay. And these are patients who you were</p> <p>3 treating for other purposes; diabetes or other</p> <p>4 conditions that came to your --</p> <p>5 A That is correct.</p> <p>6 Q I see. And so, when you've had a patient</p> <p>7 for whom you were treating for diabetes, or some</p> <p>8 other condition, indicate a desire to transition</p> <p>9 gender, indicating gender dysphoria, what do you do?</p> <p>10 A I have not had a patient that has come to</p> <p>11 me specifically in the care for, for example,</p> <p>12 diabetes, that asks me to be involved in that aspect</p> <p>13 of their care.</p> <p>14 Q So, you just -- can you say a little bit</p> <p>15 about how you come to learn that they have a desire</p> <p>16 to transition gender?</p> <p>17 A I would say that I don't have absolute</p> <p>18 confidence that they have that problem. The only</p> <p>19 expertise or the only knowledge I have is when they</p> <p>20 subsequently are referred to the other component of</p> <p>21 our practice that addresses that issue.</p> <p>22 Q Okay. Who refers them to that other part</p> <p>23 of your practice that addresses that issue?</p> <p>24 A Most often they self refer to that.</p> <p>25 Q Have you referred any of the patients to</p>	<p style="text-align: right;">Page 15</p> <p>1 opinion, as far as best medical practices, it wasn't</p> <p>2 in the best service of the patients that were coming</p> <p>3 for treatment.</p> <p>4 Q But that was a particular form of</p> <p>5 treatment, right, that you felt was not the best</p> <p>6 practice, right?</p> <p>7 A I'm a pediatric endocrinologist and what a</p> <p>8 pediatric endocrinologist is charged with doing is</p> <p>9 giving hormones to patients.</p> <p>10 Q That was the type of treatment that you</p> <p>11 felt was not appropriate practice?</p> <p>12 A That was the type of the treatment that I</p> <p>13 did not find sound scientific evidence supporting</p> <p>14 the beneficial outcomes for those patients, correct.</p> <p>15 Q Okay. So, I take it, given your field,</p> <p>16 you have not had occasion to diagnose anyone with</p> <p>17 gender dysphoria, is that right?</p> <p>18 A I have not been charged with that task,</p> <p>19 no.</p> <p>20 Q So, you've never diagnosed anyone?</p> <p>21 A I have not intentionally diagnosed,</p> <p>22 correct.</p> <p>23 Q Intentionally? Or, I mean,</p> <p>24 unintentionally?</p> <p>25 A I've not gone through the DSM criteria</p>
<p style="text-align: right;">Page 14</p> <p>1 the Transgender Center at Wash U?</p> <p>2 A I have not been asked to do so.</p> <p>3 Q So you have not?</p> <p>4 A That is correct.</p> <p>5 Q Have you -- so while you've come into</p> <p>6 contact with a small number of patients with gender</p> <p>7 dysphoria, you have not treated the gender</p> <p>8 dysphoria, is that correct?</p> <p>9 A That is correct.</p> <p>10 Q Okay. And do I understand you</p> <p>11 intentionally choose not to treat that condition?</p> <p>12 A That is correct.</p> <p>13 Q That's because you -- well, why don't you</p> <p>14 tell me. Why do you intentionally choose not to</p> <p>15 treat that condition?</p> <p>16 A Well, so, when I first was exposed to the</p> <p>17 question about the program that is going on now, the</p> <p>18 treatment of gender dysphoria, I was actually the</p> <p>19 chief of our division of endocrinology and I was</p> <p>20 charged with the task of actually looking at the</p> <p>21 scientific evidence supporting the guidelines that</p> <p>22 are being put forward and, as a physician scientist,</p> <p>23 I did that in a rigorous manner and I concluded that</p> <p>24 there was not enough evidence to support the</p> <p>25 treatment that was being put forward, so, in my</p>	<p style="text-align: right;">Page 16</p> <p>1 with a checklist, which is done in the clinics, to</p> <p>2 check off whether they fulfill the criteria that's</p> <p>3 in the DSM-5, no.</p> <p>4 Q Okay. I just want to make sure I'm not</p> <p>5 missing something. Did you, in some informal way,</p> <p>6 diagnose people with gender dysphoria?</p> <p>7 A Again, in the context of not having a</p> <p>8 doctor/patient relationship where I've been charged</p> <p>9 with caring for that, I have interacted with numbers</p> <p>10 of individuals that have -- one of the things that I</p> <p>11 did very early on, when I was investigating this,</p> <p>12 was to become familiar with the problem and that</p> <p>13 involved being able to meet with parents and</p> <p>14 individuals that had this particular condition. And</p> <p>15 if I were to have gone through the DSM Manual and</p> <p>16 listened to the stories that they were telling, they</p> <p>17 would have certainly fulfilled that criteria, but,</p> <p>18 again, it was not in a doctor/patient relationship,</p> <p>19 it was merely in the context of trying to understand</p> <p>20 what is going on with these children.</p> <p>21 Q I see. So you've met people that you</p> <p>22 believe probably meet the criteria but you haven't</p> <p>23 diagnosed any, is that a fair way to put it?</p> <p>24 A Correct. Again, it's the context of</p> <p>25 when -- the interactions. And I'm certainly very</p>

4 (Pages 13 to 16)

<p style="text-align: right;">Page 25</p> <p>1 clarify what you mean by formal education.</p> <p>2 Q Well, I'll ask broadly; any kind of</p> <p>3 training of any sort that a doctor would get in the</p> <p>4 course of, you know, either their initial medical</p> <p>5 education or continuing education.</p> <p>6 A So, working at a major academic</p> <p>7 institution, we're actually charged with providing</p> <p>8 medical education and so, to the extent that we've</p> <p>9 held journal clubs that we've had presentations with</p> <p>10 my colleagues where we've discussed the scientific</p> <p>11 evidence, where we've gone formally through the DSM</p> <p>12 Guidelines, where we've gone through the Endocrine</p> <p>13 Society Guidelines, that has been done at my</p> <p>14 institution. Have I sought out and gone to a</p> <p>15 separate conference related to gender dysphoria?</p> <p>16 The answer is no.</p> <p>17 Q But, at your own institution, you've</p> <p>18 participated in these interactions, these journal</p> <p>19 clubs and other activities that address gender</p> <p>20 dysphoria and the treatment for gender dysphoria?</p> <p>21 A That is a standard -- that is one of the</p> <p>22 components of what we do for all the conditions that</p> <p>23 endocrinologists are engaged in.</p> <p>24 Q Okay. Have you conducted any research</p> <p>25 related to gender dysphoria or the treatment of</p>	<p style="text-align: right;">Page 27</p> <p>1 published by other people? Is that what you mean?</p> <p>2 A So, again, we can define research in many</p> <p>3 different ways. If you're asking the question about</p> <p>4 research, about gathering information, about the</p> <p>5 evidence that's available, I've done a considerable</p> <p>6 amount of research and that has consisted of looking</p> <p>7 at what published data is available supporting the</p> <p>8 recommendations that are being made. That I would</p> <p>9 consider research, but it is not a clinical trial.</p> <p>10 Q Okay. And what people might call studies,</p> <p>11 scientific studies, have you done any scientific</p> <p>12 studies?</p> <p>13 A Again, how you define studies, again, I</p> <p>14 have not done clinical trials.</p> <p>15 Q Okay. When you were deposed in the Adams</p> <p>16 case, November, I believe it was, last year, you</p> <p>17 mentioned you were in the process of responding to a</p> <p>18 research funding announcement by the NIH to do</p> <p>19 research related to gender dysphoria or gender</p> <p>20 identity issues. Did I get that right?</p> <p>21 A Yes.</p> <p>22 Q Can you tell me the status of that?</p> <p>23 A Yes. There are a number of logistical</p> <p>24 issues that are needing to be worked out. There is</p> <p>25 no funding for that particular study going on,</p>
<p style="text-align: right;">Page 26</p> <p>1 gender dysphoria?</p> <p>2 A No formal trials, no.</p> <p>3 Q Any other research?</p> <p>4 A I've been in the area of HIV research for</p> <p>5 20 years and conducted a number of scientific</p> <p>6 studies that -- but not directly related to gender</p> <p>7 dysphoria.</p> <p>8 Q Yeah, I'm sorry if I was unclear. I</p> <p>9 didn't -- I know you've done research, but in the</p> <p>10 area of gender dysphoria, no research, is that</p> <p>11 right?</p> <p>12 A I have not done any -- I'm not a clinical</p> <p>13 trials physician scientist. I'm a bench scientist.</p> <p>14 Q What does that mean?</p> <p>15 A I conduct laboratory research, so I'm</p> <p>16 engaged in hypothesis-driven research.</p> <p>17 Q Okay. So, talking about research broadly,</p> <p>18 you haven't conducted any form of research relating</p> <p>19 to gender dysphoria, is that right?</p> <p>20 A No, I have. I would consider research in</p> <p>21 looking at the extensive literature that's there is</p> <p>22 research. It's not a randomized controlled trial,</p> <p>23 it's not a formal study, but that would fit within</p> <p>24 the domain of research.</p> <p>25 Q You mean reviewing research that was</p>	<p style="text-align: right;">Page 28</p> <p>1 recruiting the people that are going to be necessary</p> <p>2 to conduct that study, again, I'm a pediatric</p> <p>3 endocrinologist. And to my knowledge, you know,</p> <p>4 that hasn't moved much beyond the initial planning</p> <p>5 stages. The proposal itself was a suggestion to</p> <p>6 address the question of -- a very particular</p> <p>7 question of the effects of pubertal blockade on the</p> <p>8 trajectory as far as the number of individuals that</p> <p>9 went on to cross hormone therapy and those that did</p> <p>10 not.</p> <p>11 Q So, did you ever submit a proposal to NIH</p> <p>12 to do this research?</p> <p>13 A No.</p> <p>14 Q Okay. Did you ever respond to the funding</p> <p>15 announcement in any way?</p> <p>16 A Depends on how you say "respond." I've</p> <p>17 already said I did not submit a proposal. I have</p> <p>18 taken that to colleagues. In fact, I've had very</p> <p>19 recent discussions with my colleague at Washington</p> <p>20 University that is interested in starting some sort</p> <p>21 of research effort. And I could speak at length of</p> <p>22 what I've recommended to him as far as how these</p> <p>23 studies should be conducted. I've been very</p> <p>24 disappointed that the rigor -- scientific rigor</p> <p>25 that's necessary for those studies is not currently</p>

7 (Pages 25 to 28)

<p style="text-align: right;">Page 41</p> <p>1 Q Take a look.</p> <p>2 A Okay. It looks like what I put together,</p> <p>3 yes.</p> <p>4 Q Okay. Now, if we turn to your CV, which</p> <p>5 is attached.</p> <p>6 A It's not attached to this.</p> <p>7 Q Okay. Sorry.</p> <p>8 MR. JOHNSON: I can help you on that, too.</p> <p>9 MS. COOPER: Let's go off.</p> <p>10 (Discussion off the record.)</p> <p>11 Q (By Ms. Cooper) All right. Let's try this</p> <p>12 one last time. If you could turn to the CV attached</p> <p>13 to your report. Got that? And I see there are</p> <p>14 various publications listed.</p> <p>15 MR. JOHNSON: Leslie, I hate to interrupt</p> <p>16 you, maybe I have an incomplete copy, or maybe</p> <p>17 it's double-sided. Hold on.</p> <p>18 MS. COOPER: Is it missing --</p> <p>19 MR. JOHNSON: I think we're all right.</p> <p>20 MS. COOPER: Oh, okay. We're okay.</p> <p>21 Q (By Ms. Cooper) Does yours look okay,</p> <p>22 Dr. Hruz?</p> <p>23 A I'm looking through all of it.</p> <p>24 MR. JOHNSON: Okay. I apologize. It's</p> <p>25 all there. Thank you.</p>	<p style="text-align: right;">Page 43</p> <p>1 somebody that called me up and said, Could you</p> <p>2 comment on this clinical domain here? And it</p> <p>3 varies. But I think it's just a way that we try to</p> <p>4 distinguish from those.</p> <p>5 Q Okay. It doesn't have to do with peer</p> <p>6 review, does it; the distinction between the two</p> <p>7 categories?</p> <p>8 A Every paper here is always peer reviewed.</p> <p>9 The extent of the peer reviews varies. Some of them</p> <p>10 are peer reviewed by a number of investigators in</p> <p>11 the field. They're sent out for comments. Some are</p> <p>12 done at the editorial level. Depends on the nature</p> <p>13 of the publication. All of them, actually, go</p> <p>14 through for accuracy and content there to make sure</p> <p>15 that it's -- can be substantiated, everything that</p> <p>16 I've said there, so there's a level of review that</p> <p>17 goes on to every single publication.</p> <p>18 Q Okay. And have you published any</p> <p>19 peer-reviewed scientific articles on gender</p> <p>20 dysphoria or transgender-related issues?</p> <p>21 A There's only two papers on this CV here</p> <p>22 that relate to the area of gender dysphoria. One is</p> <p>23 No. 11. And No. 13 on the invited publication list.</p> <p>24 Q And just for the record, the No. 11 is the</p> <p>25 article called Growing Pains, Problems with Pubertal</p>
<p style="text-align: right;">Page 42</p> <p>1 Q (By Ms. Cooper) So, Doctor, my first</p> <p>2 question for you, when you get to the publications</p> <p>3 section towards the end of your CV, you have a</p> <p>4 category called publications and then, a few pages</p> <p>5 later, a category called invited publications. Can</p> <p>6 you tell me, what's the difference between those two</p> <p>7 categories to you?</p> <p>8 A Generally, I segregate out review articles</p> <p>9 and those types of things from the general</p> <p>10 publications that I have, which I've listed there.</p> <p>11 So these are a separate category that were required.</p> <p>12 It's a standard format that we have for our</p> <p>13 university as far as designating review articles</p> <p>14 versus clinical trials.</p> <p>15 Q So, the invited publications are the</p> <p>16 review articles?</p> <p>17 A That's correct.</p> <p>18 Q And the other --</p> <p>19 A And it includes things where, for example,</p> <p>20 most of this is -- the first 50 publications are</p> <p>21 things that I submitted directly to the journals for</p> <p>22 publication. The ones in invited publications are</p> <p>23 when either it's a review article that I submit to a</p> <p>24 journal or somebody asks me to contribute, for</p> <p>25 example, I've got the commentary in there, that was</p>	<p style="text-align: right;">Page 44</p> <p>1 Suppression in Treating Gender Dysphoria, published</p> <p>2 by The New Atlantis. And No. 13 is The Use of</p> <p>3 cross-sex Steroids in Treating Gender Dysphoria,</p> <p>4 published by The National Catholic Bioethics</p> <p>5 Quarterly, is that correct?</p> <p>6 A That is correct.</p> <p>7 Q Thank you. And these are -- actually,</p> <p>8 before I move on to talk about those, have you</p> <p>9 submitted any articles on transgender issues or</p> <p>10 gender dysphoria for publication that weren't</p> <p>11 accepted by any journals?</p> <p>12 A No, I've never had one that was not</p> <p>13 accepted. I'm in the process of writing a paper, as</p> <p>14 we speak, on the issues of experimentation and the</p> <p>15 parameters that are necessary for conducting trials</p> <p>16 in this domain.</p> <p>17 Q Okay. You're in the process of writing</p> <p>18 it, you said?</p> <p>19 A That's correct.</p> <p>20 Q So you haven't submitted it to anybody?</p> <p>21 A That's correct. It's due within the next</p> <p>22 several months. I'm probably going to be late in</p> <p>23 getting it, but --</p> <p>24 Q Was that an invited paper?</p> <p>25 A Yes.</p>

11 (Pages 41 to 44)

<p style="text-align: right;">Page 49</p> <p>1 people in the field, but I think the editors that</p> <p>2 were reviewing the factual information that was</p> <p>3 present were not pediatric endocrinologists.</p> <p>4 Q So, well, I'd asked whether it was peer</p> <p>5 reviewed. So is it peer reviewed; The New Atlantis</p> <p>6 article?</p> <p>7 A On that definition, it was not reviewed by</p> <p>8 other pediatric endocrinologists, to my knowledge.</p> <p>9 Q That's the definition you understand to be</p> <p>10 the definition in the field?</p> <p>11 A As we're discussing it currently, right</p> <p>12 now, yes.</p> <p>13 Q Okay. And The New Atlantis was founded by</p> <p>14 The Ethics and Public Policy Center, is that right?</p> <p>15 A I believe that that is correct.</p> <p>16 Q Okay. And that's a center dedicated to</p> <p>17 applying the Judao-Christian moral tradition to</p> <p>18 critical issues of public policy, is that your</p> <p>19 understanding?</p> <p>20 A I believe that question came up at the</p> <p>21 last deposition and I believe that that's an</p> <p>22 accurate statement.</p> <p>23 Q And your co-authors of the Growing Pains</p> <p>24 article are Lawrence Mayer and Paul McHugh, is that</p> <p>25 right?</p>	<p style="text-align: right;">Page 51</p> <p>1 Q And who was the editor?</p> <p>2 A Adam Keiper.</p> <p>3 Q And how did he know of you?</p> <p>4 A You'd have to ask him.</p> <p>5 Q Okay. Let's mark as Exhibit 2 the second</p> <p>6 article that you mentioned; The Use of cross-sex</p> <p>7 Steroids in the Treatment of Gender Dysphoria.</p> <p>8 (Deposition Exhibit 2 marked.)</p> <p>9 Q Thank you. Is that a copy of your article</p> <p>10 that was Item No. 13 on your invited publication</p> <p>11 list on your CV?</p> <p>12 A It certainly looks like it.</p> <p>13 Q And that was published in 2018?</p> <p>14 A That's correct.</p> <p>15 Q And it was published by The National</p> <p>16 Catholic Bioethics Quarterly? That's the full name</p> <p>17 of the journal?</p> <p>18 A That's correct.</p> <p>19 Q Okay. Is that a peer-reviewed, scientific</p> <p>20 journal?</p> <p>21 A In the context of what we're talking</p> <p>22 about, no.</p> <p>23 Q Okay. Meaning it was not sent out for</p> <p>24 external review by peers in your field?</p> <p>25 A That's correct. And I talked to the</p>
<p style="text-align: right;">Page 50</p> <p>1 A That is correct.</p> <p>2 Q How did you come to meet them?</p> <p>3 A I believe I was approached -- again, this</p> <p>4 is going back a couple years. The editor of the</p> <p>5 publication contacted me, asking me, within my realm</p> <p>6 as a pediatric endocrinologist, if I would be</p> <p>7 willing to discuss this particular question and we</p> <p>8 had a meeting with the eventual co-authors where we</p> <p>9 discussed the status of the science. I think the</p> <p>10 editor himself was aware of some of the concerns</p> <p>11 that I had put forward in relation to the treatment</p> <p>12 that was going on. I am not fully aware of how that</p> <p>13 came about, that he contacted me, but that is how</p> <p>14 this particular publication came to be. We had a</p> <p>15 meeting to discuss our shared concerns about the</p> <p>16 lack of scientific evidence that was out there in</p> <p>17 this particular field, felt that there was a strong</p> <p>18 need to be able to convey that and be able to set</p> <p>19 forward some of the things that needed to be done at</p> <p>20 the scientific level to enter this area of</p> <p>21 intervention in line with other areas of medicine.</p> <p>22 Q Okay. What year was this that you first</p> <p>23 were contacted by the editor of the journal?</p> <p>24 A This was published in 2017, so I believe</p> <p>25 it was near the end of 2016.</p>	<p style="text-align: right;">Page 52</p> <p>1 editor about doing that and he indicated that he</p> <p>2 was -- felt that it was of sufficient quality, after</p> <p>3 looking through the data that was there, that he</p> <p>4 made a decision not to do that. I think in this</p> <p>5 journal itself, I think that very frequently these</p> <p>6 are sent out to peers and, again, what happened at</p> <p>7 the editorial level, I'm -- I don't know all the</p> <p>8 details of that.</p> <p>9 Q Okay. We'll come back to that in a</p> <p>10 minute. I just have a few other questions first.</p> <p>11 Have you given any presentations about gender</p> <p>12 dysphoria or transgender people or related issues at</p> <p>13 scientific or medical conferences or events?</p> <p>14 A I've certainly given them at medical grand</p> <p>15 rounds in a variety of venues. I think, from the</p> <p>16 scientific standpoint, at national meetings, I've</p> <p>17 not been invited to do so, at least to this point in</p> <p>18 time.</p> <p>19 Q And where have you done medical grand</p> <p>20 rounds on this topic?</p> <p>21 A I think I listed them on my CV. Didn't I?</p> <p>22 It was St. Louis University. I'm going, actually,</p> <p>23 next week to Texas Tech to give another talk.</p> <p>24 Q And that's on gender dysphoria?</p> <p>25 A Yes.</p>

13 (Pages 49 to 52)

<p style="text-align: right;">Page 65</p> <p>1 court in any of these cases, is that right?</p> <p>2 A I've already said that I don't -- I never</p> <p>3 testified at trial.</p> <p>4 Q Okay. Do you consider yourself to be an</p> <p>5 expert on treatment of gender dysphoria?</p> <p>6 A I would say that I probably have more</p> <p>7 information about the scientific literature than</p> <p>8 most of my colleagues in pediatric endocrinology</p> <p>9 that I talk to across the country.</p> <p>10 Q Is that a yes?</p> <p>11 A Yes.</p> <p>12 Q Do you consider yourself to be an expert</p> <p>13 on the treatment of gender dysphoria in adults?</p> <p>14 A To the extent that the literature that</p> <p>15 I've reviewed addresses the issues involved in</p> <p>16 adults, yes.</p> <p>17 Q And what makes you an expert on this</p> <p>18 topic?</p> <p>19 A You know, people can define expertise in</p> <p>20 many different ways. I'm a physician scientist who</p> <p>21 has participated in the review of clinical trials</p> <p>22 for study sections. I've been a reviewer for</p> <p>23 journals. I've looked at scientific evidence in</p> <p>24 great detail in determining the veracity or the</p> <p>25 deficiencies of scientific literature and because of</p>	<p style="text-align: right;">Page 67</p> <p>1 agreed to have it published.</p> <p>2 Q Why did you initially not intend to</p> <p>3 publish it?</p> <p>4 A I just -- I hadn't written it for that</p> <p>5 purpose. I wrote it as the final exam for the</p> <p>6 course. It wasn't that I had no desire to publish</p> <p>7 it. It hadn't occurred to me that it would be</p> <p>8 wanted to be published.</p> <p>9 Q I'm sorry if I missed this, when was this</p> <p>10 course?</p> <p>11 A This was last year.</p> <p>12 Q Where did you take this course?</p> <p>13 A It was a correspondence course with two</p> <p>14 separate meetings where I got to travel to Arizona</p> <p>15 and Philadelphia, but most of it was online.</p> <p>16 Q What institution?</p> <p>17 A The National Catholic Bioethics Center.</p> <p>18 Q They teach -- they provide the coursework?</p> <p>19 A That's correct. I actually looked at a</p> <p>20 number of different ways to get this education that</p> <p>21 would fit with my schedule, and for the questions</p> <p>22 that I was asking, and this was the best option that</p> <p>23 was available to allow me to get the expertise in</p> <p>24 some of these ethical issues to help me in some of</p> <p>25 the questions that I was still asking.</p>
<p style="text-align: right;">Page 66</p> <p>1 my necessity of investigating the specifics of</p> <p>2 gender dysphoria in my relation to my role as a</p> <p>3 division chief, as I mentioned earlier, that I have</p> <p>4 extensively read the literature and have detailed</p> <p>5 knowledge of the quality of the science that's</p> <p>6 present. In that domain, I have expertise to be</p> <p>7 able to speak in this matter.</p> <p>8 Q Let's go back to what we've marked as</p> <p>9 Exhibit 2; The Use of cross-sex Steroids in the</p> <p>10 Treatment of Gender Dysphoria. I have some</p> <p>11 questions about this. You mentioned it was</p> <p>12 published by The National Catholic -- sorry, The</p> <p>13 National Catholic Bioethics Quarterly. That's a</p> <p>14 journal that integrates Christian faith and science,</p> <p>15 is that right?</p> <p>16 A This is a journal that addresses areas of</p> <p>17 medical ethics. The context of this is that,</p> <p>18 recognizing that much of the discussion that I was</p> <p>19 being involved with required more formal education</p> <p>20 in the area of bioethics prompted me to take a</p> <p>21 formal course on bioethics. This paper came out as</p> <p>22 the final exam paper that I wrote. Never intended</p> <p>23 that I was going to publish it, but it was of the</p> <p>24 quality that the editor felt very strongly that this</p> <p>25 is something that needed to be published and I</p>	<p style="text-align: right;">Page 68</p> <p>1 Q Okay. So, The National Council -- The</p> <p>2 National Catholic Bioethics Center did the course as</p> <p>3 a correspondence course, but you had some in-person</p> <p>4 portion of the training?</p> <p>5 A Two separate; one at the very beginning</p> <p>6 and one at the very end, correct.</p> <p>7 Q You said one was Arizona and one was?</p> <p>8 A Philadelphia.</p> <p>9 Q Philadelphia. Okay. And were the other</p> <p>10 students who were taking the course also present</p> <p>11 during those meetings in Arizona and Philadelphia?</p> <p>12 A Yes.</p> <p>13 Q Okay. Was Dr. Sutphin one of those</p> <p>14 students?</p> <p>15 A I don't recall, no.</p> <p>16 Q Do you know Dr. Sutphin?</p> <p>17 A No.</p> <p>18 Q You've never met -- okay. So, going back</p> <p>19 to a question I asked before, I'm not sure I heard</p> <p>20 an answer, The National Catholic Bioethics</p> <p>21 Quarterly, I asked if it's a journal that integrates</p> <p>22 Christian faith and science. Is that your</p> <p>23 understanding of the journal; that it does or</p> <p>24 doesn't?</p> <p>25 A I think it's a journal that publishes</p>

17 (Pages 65 to 68)

<p style="text-align: right;">Page 93</p> <p>1 that it was not -- not the driving decision-making</p> <p>2 factor, being honest about -- to the extent that</p> <p>3 they're not in contradiction and that that came up</p> <p>4 in the topic of conversation, at the end of the day,</p> <p>5 my recollection of this meeting was not that I</p> <p>6 objected or that anyone in the room objected on the</p> <p>7 basis of faith-based reasons. It was solely based</p> <p>8 upon the objections from the lack of scientific</p> <p>9 information.</p> <p>10 Q Okay. Can we turn to Page 665 of the same</p> <p>11 article? Oh, thank you for reminding me. Let's</p> <p>12 take a break. This is a fine breaking point.</p> <p>13 Sorry.</p> <p>14 (Break Taken.)</p> <p>15 Q Let's go back on. Returning to your</p> <p>16 article, The Use of cross-sex Steroids in Gender</p> <p>17 Dysphoria, Exhibit 2, if you can turn to Page 665.</p> <p>18 And I'm going to read a passage that I have some</p> <p>19 questions about, under the heading, Biological Sex</p> <p>20 and Anthropology. Okay. If you'll read along with</p> <p>21 me; Before exploring the medical aspects of cross</p> <p>22 hormone administration, consideration of the basic</p> <p>23 biology of human sexuality exposes a violent</p> <p>24 distortion of fundamental anthropological principles</p> <p>25 in the new gender mentality. Reproduction is the</p>	<p style="text-align: right;">Page 95</p> <p>1 female does not mean what male and female means is</p> <p>2 an irrational statement. When you reject or try to</p> <p>3 re-define what maleness is from a biological</p> <p>4 standpoint, or femaleness is, that is the error that</p> <p>5 is being made there.</p> <p>6 Q What do you mean by the term "biological</p> <p>7 mutiny"?</p> <p>8 A I think it's a rejection of basic</p> <p>9 biological facts. So the arguments that are put</p> <p>10 forward from the ideological perspective and the</p> <p>11 non-scientific realm, you know, the attempt that</p> <p>12 I've made, many times, is to understand the logical</p> <p>13 thinking that's involved, or I should say illogical</p> <p>14 thinking that's involved in there, that were put</p> <p>15 forward statements trying to conflate or distort</p> <p>16 what we mean by sex. And including statements that</p> <p>17 are made that gender is sex. It is -- the only</p> <p>18 potential explanation that I've been able to come up</p> <p>19 with is that that is based upon that rejection of</p> <p>20 that fundamental understanding of what sex is.</p> <p>21 Q Is that a term you coined; biological</p> <p>22 mutiny, or does it come from some other context?</p> <p>23 A You know, when I wrote that, it was put in</p> <p>24 quotes because I remember hearing it somewhere. I</p> <p>25 couldn't cite anybody in particular. That term</p>
<p style="text-align: right;">Page 94</p> <p>1 primary purpose of sex, not just in humans but also</p> <p>2 across the entire animal kingdom. It is objectively</p> <p>3 irrational to accommodate contrary thinking by</p> <p>4 rejecting a male or female body that is fully</p> <p>5 competent with respect to its innate reproductive</p> <p>6 purpose. Cross sex hormones, by their very nature,</p> <p>7 render an individual incapable of fulfilling the</p> <p>8 intrinsic biological role of the human body as male</p> <p>9 or female. Although potentially reversible after a</p> <p>10 short-term administration, the effects of cross-sex</p> <p>11 steroids on fertility are expected to be permanent</p> <p>12 when treatment is started in children. The</p> <p>13 readily-accepted view that reproductive capacity can</p> <p>14 be disassociated from what it means to be male and</p> <p>15 female, which has grown from the seeds of, quote,</p> <p>16 biological mutiny, closed quote, that began with the</p> <p>17 acceptance of contraception as a solution to</p> <p>18 difficult social circumstances must be held to close</p> <p>19 scrutiny in assessing the morality of cross-sex</p> <p>20 steroid use. Okay. My first question: What do you</p> <p>21 mean by it is objectively irrational to reject a</p> <p>22 male or female body that is fully competent with</p> <p>23 respect to its innate reproductive purpose?</p> <p>24 A Similar to what we've previously</p> <p>25 discussed, I think to make the claim that male and</p>	<p style="text-align: right;">Page 96</p> <p>1 seemed to ring a bell; as far as it's the rejection</p> <p>2 of what's obviously true, from a scientific</p> <p>3 biological perspective, and that's the basis that</p> <p>4 allows one to put forward an ideology that -- that</p> <p>5 basically says that you can define sex as any way</p> <p>6 that you'd like.</p> <p>7 Q When did you first come to consider</p> <p>8 transition-affirming treatment to be, quote,</p> <p>9 biological mutiny?</p> <p>10 A I can't define a particular time that I</p> <p>11 did this. I think, as I served as an expert witness</p> <p>12 in earlier cases, was to the extent that I had seen</p> <p>13 statements made by other so-called experts that were</p> <p>14 starting to make these claims that reproductive</p> <p>15 capacity had nothing to do with sex; that it could</p> <p>16 be defined in all of these other ways that reached</p> <p>17 the level that I would put in the strong term of</p> <p>18 mutiny to be able to come to that conclusion. I</p> <p>19 think it was probably in the context of my serving</p> <p>20 as an expert witness in seeing other people putting</p> <p>21 forward this ideology that began to seem so contrary</p> <p>22 to what we understand from a scientific perspective.</p> <p>23 Q So you point to contraception as an</p> <p>24 example of biological mutiny. Can you explain that?</p> <p>25 A So, the ability to separate out the</p>

24 (Pages 93 to 96)

<p style="text-align: right;">Page 173</p> <p>1 contributing factors differ from one individual to</p> <p>2 another, both in magnitude and actuality, that your</p> <p>3 approach to treatment may differ based on that until</p> <p>4 we have information about what those factors are and</p> <p>5 how they respond, we're never going to get an</p> <p>6 answer.</p> <p>7 Q So, for adults that have persisted and</p> <p>8 they're well past puberty and maintain a</p> <p>9 cross-gender identification, transgender</p> <p>10 identification, I'm still trying to understand what</p> <p>11 you consider appropriate interventions, if any, for</p> <p>12 that population of patients.</p> <p>13 A I would say that we don't have the</p> <p>14 definitive answer of what the therapy is and that</p> <p>15 it's a topic of research, and any patient that is</p> <p>16 enrolled in any intervention should be under the</p> <p>17 auspices of an IRB with a carefully controlled trial</p> <p>18 that's going to help allow us to get that</p> <p>19 information.</p> <p>20 Q What's an IRB?</p> <p>21 A Institutional Review Board.</p> <p>22 Q So, sitting here now, you couldn't say the</p> <p>23 appropriate treatment for adults with gender</p> <p>24 dysphoria includes counseling to alleviate the -- or</p> <p>25 to align the gender identity with the sex assigned</p>	<p style="text-align: right;">Page 175</p> <p>1 A That is, again, looking at whether you're</p> <p>2 looking at long term or short term. And the same</p> <p>3 deficiencies, the same studies that report compared</p> <p>4 to the background population, as far as quality of</p> <p>5 life, that they still suffer from many of these</p> <p>6 other morbidities. And to the extent that that's</p> <p>7 put forward that that's social stress versus the</p> <p>8 underlying difficulty that the person is</p> <p>9 experiencing has not been rigorously studied in</p> <p>10 science.</p> <p>11 Q So, at this point, given the information</p> <p>12 that we have from research that's been done, your</p> <p>13 view is we don't have scientific validation of --</p> <p>14 that treatment through hormone therapy or surgeries</p> <p>15 alleviates gender dysphoria in the long term, is</p> <p>16 that right?</p> <p>17 A Yes.</p> <p>18 Q Okay. That being said, is it your view</p> <p>19 that that's, therefore, an inappropriate treatment</p> <p>20 to offer adults with gender dysphoria?</p> <p>21 A My opinion is that it's inappropriate to</p> <p>22 present it as a definitive answer when we don't have</p> <p>23 that answer and that if you're going to offer that</p> <p>24 intervention, it needs to be known that this is</p> <p>25 essentially experimental intervention.</p>
<p style="text-align: right;">Page 174</p> <p>1 at birth?</p> <p>2 A I think most professionals say it includes</p> <p>3 that, but if that's the sole response or the extent</p> <p>4 that hormone therapy, you know, is a part of that</p> <p>5 therapy, the answer is not there.</p> <p>6 Q I'm going to ask it different because I'm</p> <p>7 not sure I understood the answer there. Is it your</p> <p>8 view that there's just no known intervention or</p> <p>9 treatment that is effective to treat adults with</p> <p>10 gender dysphoria at this point?</p> <p>11 A It gets back to how you define effective.</p> <p>12 But there is no data that suggests the intended goal</p> <p>13 of preventing suicide, long term, you know, the</p> <p>14 interventions that we have right now, solves that</p> <p>15 problem. If the trial had been done in a</p> <p>16 randomized, controlled manner, you could look at</p> <p>17 current interventions and say, What is the rate of</p> <p>18 suicide in the group that received that intervention</p> <p>19 versus those that didn't? That's what needs to be</p> <p>20 there to answer that question. That data is not</p> <p>21 there.</p> <p>22 Q Is there data on quality of life of people</p> <p>23 who have had hormone therapy?</p> <p>24 A There is.</p> <p>25 Q What does that show?</p>	<p style="text-align: right;">Page 176</p> <p>1 Q Okay. So, the intervention that -- is</p> <p>2 there any kind of intervention you think is</p> <p>3 appropriate to offer adults with gender dysphoria?</p> <p>4 A I think it's very appropriate, that</p> <p>5 includes everything that we've talked about here, to</p> <p>6 study that in the scientific realm to see if it</p> <p>7 actually provides the benefit we're looking at.</p> <p>8 Q But right now, before we have additional</p> <p>9 studies that are not currently available to us, do</p> <p>10 you think it's appropriate to offer patients with</p> <p>11 gender dysphoria, who are adults, any particular</p> <p>12 intervention or treatment?</p> <p>13 A Not any particular intervention. I</p> <p>14 believe that would be -- they would be best served</p> <p>15 by approaching this, and, again, what goes on in a</p> <p>16 clinical trial versus what goes on in a</p> <p>17 doctor/patient relationship and a patient in the</p> <p>18 office are two different questions. The</p> <p>19 stipulations of the Belmont Report state very</p> <p>20 clearly there are many things that go on in a</p> <p>21 doctor/patient relationship where we do therapies</p> <p>22 that are not proven and the directive there is that</p> <p>23 when engaging in a situation with a patient in your</p> <p>24 office, that it is necessary to move beyond that to</p> <p>25 get that general information.</p>

44 (Pages 173 to 176)

<p style="text-align: right;">Page 197</p> <p>1 to happen.</p> <p>2 Q Okay. So, it's not, in your view, a</p> <p>3 criteria, a proved requisite to recommending a</p> <p>4 treatment, that it's been through randomized</p> <p>5 controlled trials that compare the outcomes of the</p> <p>6 treatment with other treatment modalities?</p> <p>7 A In all of medicine, we do many things that</p> <p>8 don't have answers. That's why I'm in business as a</p> <p>9 physician scientist; to answer questions to medical</p> <p>10 problems that we don't have solutions to and we</p> <p>11 don't sit back and do nothing on these individuals,</p> <p>12 but we don't claim medical necessity for</p> <p>13 interventions that have not been proven</p> <p>14 definitively.</p> <p>15 Q So is your answer, yes, you don't limit</p> <p>16 your treatment exclusively to treatments that have</p> <p>17 been through randomized controlled trials comparing</p> <p>18 outcomes of the treatments with other treatment</p> <p>19 modalities?</p> <p>20 A Yes, that's true.</p> <p>21 Q And do you limit your treatments to those</p> <p>22 that have been proven effective long term?</p> <p>23 A We -- the strength of the recommendation</p> <p>24 depends on what I'm addressing and what are the</p> <p>25 risks and benefits, both short term and long term.</p>	<p style="text-align: right;">Page 199</p> <p>1 No. But there's long-term data that's been looked</p> <p>2 at, and there's actually ongoing questions about the</p> <p>3 effects of that particular intervention. And it's</p> <p>4 also very important, when we're talking about that</p> <p>5 as well, is that we're looking at intervening in a</p> <p>6 developmental process that is happening due to a</p> <p>7 pathologic condition, abnormally, rather than</p> <p>8 intervening with a pubertal blockade in a normal</p> <p>9 pubertal process that happens with all the signal</p> <p>10 processes moving forward normally.</p> <p>11 Q Understood. So how -- when you say</p> <p>12 there's been research on the long-term effects, how</p> <p>13 far out into adulthood do those studies go?</p> <p>14 A The ones I've looked at probably go into</p> <p>15 the 20s. Looking at -- so we're talking 10, 20,</p> <p>16 maybe even 30 years. And, again, looking at what</p> <p>17 the desired outcome is, the data that we have from</p> <p>18 other conditions where you have exposure to sex</p> <p>19 steroid hormones, you know, how that interferes,</p> <p>20 we've had this question; how long do we continue</p> <p>21 therapy when we start getting into the normal</p> <p>22 adolescent years? And this is one area where I</p> <p>23 think that there's pretty clear evidence that --</p> <p>24 that bone mineral density is compromised when you</p> <p>25 continue with this pubertal blockade beyond the time</p>
<p style="text-align: right;">Page 198</p> <p>1 Q So, have you recommended treatment for any</p> <p>2 condition that has not been proven effective long</p> <p>3 term?</p> <p>4 A I've recommended it, but I've not asserted</p> <p>5 that it's medically necessary.</p> <p>6 Q Understood. Okay. And I understand</p> <p>7 puberty blockers for treatment of precocious puberty</p> <p>8 is a form of treatment that is used in your field,</p> <p>9 is that right?</p> <p>10 A That's correct.</p> <p>11 Q And that's something you have recommended</p> <p>12 for patients?</p> <p>13 A In treating precocious puberty, yes.</p> <p>14 Q Are there studies on long-term effects of</p> <p>15 puberty blockers for treating precocious puberty?</p> <p>16 A It depends on how you define long term.</p> <p>17 The goal, again, in that indication, we're looking</p> <p>18 at preserving, achieving, normal adult stature and</p> <p>19 then temporizing the pubertal changes until they</p> <p>20 reach a developmental age where they're able to</p> <p>21 manage that particular condition. There are</p> <p>22 long-term studies going on looking at the effects of</p> <p>23 that in bone mineral density. We've been doing this</p> <p>24 for many more years. Does it reach out to the time</p> <p>25 of somebody's natural death in their 80s or 90s?</p>	<p style="text-align: right;">Page 200</p> <p>1 when normal puberty would occur.</p> <p>2 Q So, focusing on the patients with</p> <p>3 precocious puberty that get puberty blockers as</p> <p>4 treatment. I think you mentioned before there was</p> <p>5 some questions -- I don't know if it was the safety</p> <p>6 or efficacy, but have any problems been identified</p> <p>7 in the research?</p> <p>8 A Again, this gets to the goal of therapy,</p> <p>9 of preventing pubertal progression until an age of</p> <p>10 normal puberty. Very well established that that is</p> <p>11 effective. There are questions about how long to</p> <p>12 continue therapy, when to initiate therapy. There's</p> <p>13 evidence that suggests that if you start it too late</p> <p>14 that you're not going to have a positive impact on</p> <p>15 final adult height. There are questions that are</p> <p>16 unanswered about whether height is actually a</p> <p>17 necessary criteria. How are people harmed by being</p> <p>18 short? Very questionable. And that's actually the</p> <p>19 basis why insurance companies have rejected pubertal</p> <p>20 blockade for patients where we can't demonstrate</p> <p>21 that that desired outcome will have a long-term</p> <p>22 effect. We have other areas as well where -- I'll</p> <p>23 leave it at that.</p> <p>24 Q So, have there been any indications of</p> <p>25 adverse health consequences for patients who had</p>

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<p style="text-align: right;">Page 225</p> <p>1 evidence that have, it looks like, two circles or</p> <p>2 sometimes one circle?</p> <p>3 MR. JOHNSON: Just for the record, when</p> <p>4 you say one circle or two circles, with or</p> <p>5 without the plus sign?</p> <p>6 MS. COOPER: Marked with a plus sign.</p> <p>7 When I say one or two circles --</p> <p>8 MR. JOHNSON: Can we try that again?</p> <p>9 MS. COOPER: Sure.</p> <p>10 Q (By Ms. Cooper) So a number of these</p> <p>11 recommendations in the guidelines from the Endocrine</p> <p>12 Society have, let's say, two filled-in circles,</p> <p>13 right? Some of them have one filled-in circle.</p> <p>14 Now, is that -- that's what leads you to read this</p> <p>15 as saying that it's relying on low-quality evidence,</p> <p>16 right?</p> <p>17 A So, that is the objective measure that</p> <p>18 they used in making the guidelines. You can go back</p> <p>19 to the actual grade system where that was reported</p> <p>20 in that and, then, beyond that, I have not just</p> <p>21 relied on the circles. I've actually gone in and</p> <p>22 looked at the actual studies that they're basing</p> <p>23 their recommendations on and the reasons why they</p> <p>24 get low and very low-quality evidence</p> <p>25 recommendations.</p>	<p style="text-align: right;">Page 227</p> <p>1 Guidelines?</p> <p>2 A Again, talking in general about clinical</p> <p>3 practice guidelines, in general, not just with the</p> <p>4 Endocrine Society but anybody that puts them</p> <p>5 forward, the advantage is that often allows one to</p> <p>6 synthesize a large body of data when most practicing</p> <p>7 physicians are not going to have the ability to read</p> <p>8 all of the primary literature. It provides an</p> <p>9 opportunity to work toward understanding what other</p> <p>10 people are putting forward as, again, from that</p> <p>11 recommendation, the advantage -- again, this is</p> <p>12 actually, a British medical journal put together a</p> <p>13 series of papers, probably a decade ago, discussing</p> <p>14 in great detail the hazards and the benefits of</p> <p>15 clinical practice guidelines. They're a starting</p> <p>16 point. They're not a definitive answer. And they</p> <p>17 provide some help but they also have been</p> <p>18 historically not validated. There's not a</p> <p>19 standardization about how these are done. There's</p> <p>20 actually symmetrics that have been done to evaluate</p> <p>21 the rigor with which -- there's actually a study</p> <p>22 that's out there where they've looked at different</p> <p>23 groups of people looking at the exact same data and</p> <p>24 coming out with different recommendations based upon</p> <p>25 that, so there's certain criteria for that. And</p>
<p style="text-align: right;">Page 226</p> <p>1 Q Do you consider the Endocrine Society's</p> <p>2 Clinical Practice Guidelines in other topics to be</p> <p>3 more reliable or useful?</p> <p>4 A I approach all clinical practice</p> <p>5 recommendations the same way; that looks at what is</p> <p>6 being proposed, what is the quality of the evidence,</p> <p>7 recognizing the benefits and the problems with</p> <p>8 clinical practice guidelines.</p> <p>9 Q So that's in any topic?</p> <p>10 A On any topic.</p> <p>11 Q Okay. Is it your view that the quality of</p> <p>12 evidence, as reflected in the marked circles in the</p> <p>13 Endocrine Society Guidelines on gender dysphoria,</p> <p>14 are lower than the quality of evidence that they</p> <p>15 have relied upon in other Endocrine Society</p> <p>16 guidelines, practice guidelines?</p> <p>17 A It's -- it runs the gamut as far as</p> <p>18 quality of evidence. That's a broad statement.</p> <p>19 There are some recommendations that have been made</p> <p>20 with similar quality evidence, in my reading of</p> <p>21 those recommendations, again, looking at</p> <p>22 risk-benefit analysis about how to act in accord</p> <p>23 with those recommendations.</p> <p>24 Q Okay. And do you follow the</p> <p>25 recommendations of other Endocrine Society</p>	<p style="text-align: right;">Page 228</p> <p>1 where we found that this has failed the medical</p> <p>2 profession is where people stop with the</p> <p>3 recommendation and don't pursue that further. They</p> <p>4 don't keep the critical eye on this and they act</p> <p>5 upon this in a way -- now, again, it depends on what</p> <p>6 the level of evidence is. Historical precedents for</p> <p>7 Clinical Practice Guidelines that were adopted as</p> <p>8 being how practitioners should approach a particular</p> <p>9 condition that were eventually proven completely</p> <p>10 false. For example, giving hormones to</p> <p>11 post-menopausal women, giving steroids to people</p> <p>12 posttraumatic spinal cord injury. There's a whole</p> <p>13 list of things that have been put forward with the</p> <p>14 evidence that was available at one particular point</p> <p>15 in time only defined as if the evidence comes</p> <p>16 forward that they were completely wrong. And that</p> <p>17 that has suggested the opposite. And usually that</p> <p>18 occurs -- usually that occurs in situations where</p> <p>19 the evidence itself is in the category that we're</p> <p>20 looking at here; low or very low-quality evidence.</p> <p>21 And, by definition, in the grade system, it says</p> <p>22 that when you have low or very low evidence of data,</p> <p>23 that it's very likely, as new data becomes</p> <p>24 available, that the recommendations will change.</p> <p>25 Q Okay. And do -- in your experience, do</p>

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<p style="text-align: right;">Page 285</p> <p>1 that was necessary for me to be able to understand a</p> <p>2 little bit more what was going on. And then the</p> <p>3 complaint, the expert declarations, the rebuttals to</p> <p>4 that, and I think everything else that I read I</p> <p>5 would have approached independent of participating</p> <p>6 in this case because of my ongoing desire to know</p> <p>7 what's going on in this field.</p> <p>8 Q You mentioned people fire you off e-mails.</p> <p>9 Do you mean from advocacy groups? Who fires you off</p> <p>10 e-mails that you were talking about?</p> <p>11 A I get these all the time in all different</p> <p>12 areas. We have -- in fact, my colleagues at</p> <p>13 Washington University will alert me to papers I</p> <p>14 have, e-mails that come out, Medscape, for example,</p> <p>15 comes out with all sorts of things that come across</p> <p>16 my desk.</p> <p>17 Q Okay. And did you -- you've reviewed the</p> <p>18 materials published by the American College of</p> <p>19 Pediatrics on gender dysphoria, isn't that right?</p> <p>20 A Yes. Yes.</p> <p>21 MS. COOPER: Let's take a break for about</p> <p>22 five minutes. Something like that. And then I</p> <p>23 think we won't have too much more.</p> <p>24 (Break Taken.)</p> <p>25 Q (By Ms. Cooper) We can go back on. We've</p>	<p style="text-align: right;">Page 287</p> <p>1 what is being done. They don't want to pay for</p> <p>2 things that are not going to have a benefit and I</p> <p>3 think that there are other things that factor in</p> <p>4 their consideration as well, including cost and</p> <p>5 logistics, allocation of scarce resources. There's</p> <p>6 all sorts of things that insurance companies use,</p> <p>7 but whether it is efficacious is certainly a</p> <p>8 consideration and it's a valid consideration.</p> <p>9 Q And whether it's efficacious could be</p> <p>10 determined by data apart from randomized clinical</p> <p>11 trials over long term, right?</p> <p>12 A It certainly is considered in short term</p> <p>13 and various end points that you have and even the</p> <p>14 strength of the data. You don't discount</p> <p>15 low-quality studies, but you don't use them as the</p> <p>16 benchmark as far as making that determination that</p> <p>17 we've solved the problem.</p> <p>18 Q So, just to be clear, it's not your</p> <p>19 understanding that insurance companies would limit</p> <p>20 insurance coverage only to those treatments that</p> <p>21 have been demonstrated to have long-term safety and</p> <p>22 effectiveness through randomized controlled clinical</p> <p>23 trials?</p> <p>24 MR. JOHNSON: Object. Lack of foundation.</p> <p>25 A Again, the considerations, I think there</p>
<p style="text-align: right;">Page 286</p> <p>1 used the term "medical necessity" in various ways</p> <p>2 and I just want to get some clarity to make sure</p> <p>3 we're on the same page. I understood you to be</p> <p>4 saying that there may be conditions for which --</p> <p>5 excuse me, let me say that again. There may be</p> <p>6 treatments where there's no randomized clinical</p> <p>7 trials demonstrating the safety and effectiveness</p> <p>8 over long term that you might still recommend for</p> <p>9 patients, but you wouldn't say it's medically</p> <p>10 necessary. Is that -- did I say that right?</p> <p>11 A Yes.</p> <p>12 Q Okay.</p> <p>13 A And, again, the caveat there is that's</p> <p>14 different than things where there's evidence that</p> <p>15 suggest it might be harmful.</p> <p>16 Q And is it your understanding that that</p> <p>17 understanding of the term "medical necessity," that</p> <p>18 something's not medically necessary if there isn't</p> <p>19 randomized controlled clinical trials demonstrating</p> <p>20 long-term safety and effectiveness. Is it your</p> <p>21 understanding that that is the definition insurance</p> <p>22 companies use in determining medical necessity?</p> <p>23 A My understanding of insurance companies is</p> <p>24 they factor in a number of different considerations</p> <p>25 and one of them is whether it is efficacious and</p>	<p style="text-align: right;">Page 288</p> <p>1 are some things that remain a mystery to me as far</p> <p>2 as why insurance companies will or will not approve</p> <p>3 of various therapies, but, again, it ultimately</p> <p>4 comes down to a risk benefit analysis with the</p> <p>5 things that they're considering, not necessarily in</p> <p>6 line with what the practitioner is in that</p> <p>7 risk-benefit analysis.</p> <p>8 Q Okay. So, is it your understanding the</p> <p>9 insurance companies will not cover treatment unless</p> <p>10 it's been definitively determined by the research</p> <p>11 community to be solved as efficacious?</p> <p>12 MR. JOHNSON: Same objection.</p> <p>13 A I don't recall ever saying that and I</p> <p>14 wouldn't say that. But I would say that it --</p> <p>15 certainly the level of information that is available</p> <p>16 will influence the decision that's made.</p> <p>17 Q (By Ms. Cooper) So it doesn't necessarily</p> <p>18 have to be research conducted by randomized clinical</p> <p>19 trials demonstrating long-term effectiveness?</p> <p>20 A It will depend upon the cost, the number</p> <p>21 of patients that are being affected by this, by not</p> <p>22 only effectiveness but also side effects of</p> <p>23 treatment that will, actually, potentially incur</p> <p>24 cost to the insurance company that's going forward</p> <p>25 with this. All of that will play a role and more.</p>

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